

Amendments to the Specification

Please replace the **ABSTRACT** with the following paragraph

ABSTRACT

Described herein are diuretic condensation aerosols and methods of making and using them. Kits for delivering a condensation aerosol are also described. The diuretic aerosols typically comprise diuretic condensation aerosol particles that comprise a diuretic compound. In some variations the diuretic compound is selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928, and BG 9719. Methods of treating edema using the described aerosols are also provided. In general, the methods typically comprise the step of administering a therapeutically effective amount of diuretic condensation aerosol to a person with edema. ~~The diuretic condensation aerosol may be administered in a single inhalation, or may be administered in more than one inhalation.~~ Methods of forming a diuretic condensation aerosol are also described. The methods typically comprise the steps of providing a diuretic composition, vaporizing the composition to form a vapor, and then condensing the diuretic composition vapor.

Please replace paragraph [0006] with the following paragraph:

[0006] In some variations, the aerosol comprises at least 50% by weight of diuretic condensation particles. In other variations the aerosol comprises at least 75% or 95% by weight of the diuretic condensation particles. Similarly, in some variations, the aerosol is substantially free of thermal degradation products, and in some variations, the diuretic condensation aerosol has a MMAD in the range of 1-3 μm . Typically, the aerosol particles have a mass median aerodynamic diameter of less than 5 microns. Preferably, the particles have a mass median aerodynamic diameter of less than 3 microns. More preferably, the particles have a mass median aerodynamic diameter of less than 2 or 1 micron(s). Typically, the aerosol particles comprise less than 10 percent by weight of a diuretic degradation product (e.g., ethacrynic acid, bumetanide, torsemide,

Serial No. 10/712,365 2
Attorney Docket No. 00065.01R

azosemide, muzolimine, piretanide and tripamide degradation products). Preferably, the particles comprise less than 5 percent by weight of a diuretic degradation product. More preferably, the particles comprise less than 2.5, 1, 0.5, 0.1 or 0.03 percent by weight of a diuretic degradation product.

Please replace paragraph [0098] with the following paragraph:

[0098] About 1.1 mg of ethacrynic acid (MW 303, melting point 122 °C, oral dose 25 mg) was dip coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 1.32 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron Teflon TEFLON® filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The Teflon TEFLON® filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 99.83% ethacrynic acid.

Please replace paragraph [0100] with the following paragraph:

[0100] About 1.01 mg of ethacrynic acid (MW 303, melting point 122 °C, oral dose 25 mg) was dip coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 1.21 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad

Serial No. 10/712,365 3
Attorney Docket No. 00065.01R

capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron Teflon TEFLON[®] filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The Teflon TEFLON[®] filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 99.57% ethacrynic acid.

Please replace paragraph [0101] with the following paragraph:

[0101] About 1.09 mg of bumetanide (MW 364, melting point 231 °C, oral dose 0.5 mg) was dip coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 1.3 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron Teflon TEFLON[®] filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The Teflon TEFLON[®] filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 98.44% bumetanide.

Please replace paragraph [0103] with the following paragraph:

Serial No. 10/712,365 4
Attorney Docket No. 00065.01R

[0103] About 0.71 mg of spironolactone (MW 417, melting point 135 °C, oral dose 25 mg) was dip coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 0.85 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron Teflon TEFLON® filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The Teflon TEFLON® filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 100% spironolactone.

Please replace paragraph [0104] with the following paragraph:

[0104] About 0.84 mg of spironolactone (MW 417, melting point 135 °C, oral dose 25 mg) was dip coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 1.01 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron Teflon TEFLON® filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The Teflon TEFLON® filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 100% spironolactone.

Serial No. 10/712,365 5
Attorney Docket No. 00065.01R

Please replace paragraph [0105] with the following paragraph:

[0105] About 0.733 mg of triamterene (MW 253, melting point 316 °C, oral dose 100 mg) was dissolved in 50 µl of 88% formic acid and dripped onto the stainless steel surface of a flashbar apparatus at a thickness of about 0.97 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron ~~Teflon~~ TEFLON[®] filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about 200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The ~~Teflon~~ TEFLON[®] filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 99.76% triamterene.

Please replace paragraph [0106] with the following paragraph:

[0106] About 0.841 mg of triamterene (MW 253, melting point 316 °C, oral dose 100 mg) was manually coated onto the stainless steel surface of a flashbar apparatus at a thickness of about 1.11 µm. (The flashbar is a cylinder 3.5 cm long and 1.3 cm in diameter consisting of a hollow tube of 0.005" thick stainless steel.) Brass electrodes were connected to either end of the steel cylinder. The coated flashbar was secured in an electrical mount, which connected to two 1.0 Farad capacitors in parallel. An airway was provided by a 2 cm diameter glass sleeve placed around the flashbar. 15 L/min of room air were pulled by a house vacuum through the vaporization chamber and a filter housing, which contained a two-micron ~~Teflon~~ TEFLON[®] filter. A power supply charged the capacitors to 20.5 volts, at which point the circuit was closed with a switch and the stainless steel flashbar was resistively heated to about 400 °C within about

Serial No. 10/712,365 6
Attorney Docket No. 00065.01R

200 milliseconds. The drug aerosolized and flowed through the airway and into the filter. The ~~Teflon~~ TEFLON[®] filter was extracted with 5 mL of acetonitrile, and the sample was run through an HPLC for purity analysis. Purity analysis indicated that the aerosol was 100% triamterene.

Serial No. 10/712,365 7
Attorney Docket No. 00065.01R